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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,396	08/20/2004	Michihiko Kataoka	21146 US (C038435/0178278)	5970
7590 07/26/2006			EXAMINER	
Stephen M Haracz Bryan Cave 1290 Avenue of the Americas New York, NY 10104-3300			SINGH, SATYENDRA K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/505,396	KATAOKA ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 1-5 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/20/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary amendments to the claims filed by applicants on August 20th 2006 are duly acknowledged.

Claims 1-14 are examined on their merits, herein.

Claim Objections

1. Claims 1, 5, and 7 are objected to because of the following informalities: Claims recite the limitation of the molecular mass of an isolated enone reductase enzyme using **parenthesis**, which is improper. If applicants intend to appropriately require the limitations (currently presented within parenthesis) to be considered for the invention as claimed, they are requested to remove the parenthesis and amend the claims appropriately. Appropriate correction is required.

2. Claims 2, 3, and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2, 3, and 4 recite "An enone reductase" according to claims 1, or 2, which fails to further limit the invention of broader claims on which the claims 2, 3, and 4 depend from. Appropriate ("The enone reductase") correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most connected, to make and/or use the invention.

The invention appears to employ novel biological material, *Candida kefir* (*Candida macedoniensis*) IFO 0960. Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological material is not so obtainable or available, the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the biological material. The specification does not disclose a repeatable process to obtain the biological material and it is not apparent if the biological material is readily available to the public.

It is noted that applicant disclosed the biological material (see instant specification, page no. 2, lines 17-23, in particular), but there is no indication in the specification as to whether the deposit was made under Budapest treaty and as to its public availability. If the deposit is made under the Budapest Treaty, then an **affidavit or declaration** by applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological material (in the instant case *Candida kefir*, *Candida macedoniensis*, IFO 0960) has been deposited under the Budapest Treaty and that the biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. §1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification should be amended to include this information, however, applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims recite the limitation of "an enone reductase having the following physico-chemical properties: a) molecular mass: $61,3000 \pm 5,000$ Da (**consisting of one subunit** having a molecular mass of $45,000 \pm 5,000$ Da)", which is confusing. First, it is not clear whether the enzyme, enone reductase as claimed has only one subunit /polypeptide or it has more than one subunits because the discrepancy between the molecular masses recited in claimed invention for the same enzyme/polypeptide (especially in view of the fact that applicant's state that the enzyme of the instant invention consists of a **single subunit** of 45 KDa under denaturing electrophoretic conditions; see page 1, lines 10-16, in particular). Second, it is not clear

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whether the two molecular masses recited in the claims actually refer to the same component or isolated enzyme preparation, or to a different composition of the enzyme.

In view of the disclosure provided by applicants (see instant specification, page 1, 3rd paragraph, in particular and the entire disclosure in general), it appears that the same polypeptide/subunit has two different molecular weights under two very different biochemical conditions (i.e. relatively higher calculated molecular weight under gel filtration conditions as compared to under denaturing electrophoretic conditions, such as SDS-PAGE). Therefore, applicants are required to either provide an appropriate explanation, or amend the claims appropriately in order to address the ambiguity (as cited *supra*) in the claimed invention. Appropriate explanation and correction is required.

Since claims 2-4, 6, and 8-14 depend (directly or indirectly) from the broader claims 1, 5, and 7, they are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-4 and 7-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-8 of copending Application No. 10/528,960 (same inventive entity, common assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because the enone reductase polypeptide product of the isolated DNA and the process of use in the production of levodione using such enzyme product that has identical physico-chemical properties (including molecular mass, temperature and pH optima, substrate specificity, and co-factor requirements) as claimed in the invention of the instant application. The specific process steps claimed in the applications would have been a matter of routine optimization for a person of ordinary skill in the art at the time this invention was made (as evident by the disclosure of the prior art submitted by the applicants; see Fukuoka et al; IDS; EP 1,074,630).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 7-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/505,314 (common inventor, same assignee). Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application are also directed to a process for producing levodione from ketoisophorone using an isolated enone reductase having identical physico-chemical properties as claimed in the instant invention. The specific process steps claimed in the applications would have been a matter of routine optimization for a person of ordinary skill in the art at the time this invention was made (as evident by the disclosure of the prior art submitted by the applicants; see Fukuoka et al; IDS; EP 1,074,630).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO claims are allowed.

Pertinent prior art not relied upon in the Rejections


1. Fukuoka et al (EP 1,074,630 A3; IDS): Microbial production of levodione.
2. Yamamoto et al. (US 6,780,976 B2; issued on Aug 24, 2004): Enone reductases, methods for producing same, and methods for selectively reducing a carbon-carbon double bond of an alpha, beta-unsaturated ketone using the reductases.

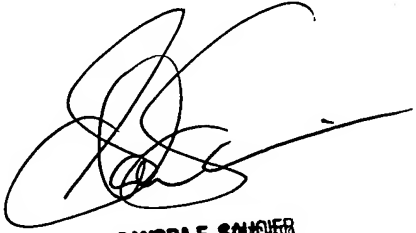
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Satyendra K. Singh
Patent Examiner
Art Unit 1651


SANDRA E. SAWYER
PRIMARY EXAMINER